

K901982

510(k) Summary
3-Way Stopcock

FEB 21 1997

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Tri-Flow™ 3-Way Stopcock is a stopcock as classified in 21 CFR §880.5440.

The Tri-Flow™ 3-Way Stopcock is substantially equivalent to the following legally marketed devices: Medex, Inc. 3-Way stopcock, North American Instrument Corporation stopcock, and Tronomed/Mallinckrodt stopcock..

The Tri-Flow™ 3-Way Stopcock is a disposable stopcock designed for one time use. The device consists of three injection molded components: a body, a stem/handle, and a swivel nut. A small amount of medical grade fluid is used as a lubricant to reduce friction at the stem/body interface. The body contains four channels for fluid flow. Three channels end in female luer ports and the other channel terminates as a male luer port. The swivel nut is press fit onto the male luer port. The stopcock body has a cylindrical bore intersecting all four channels into which the stem/handle is press fit mounted. The stem/handle contains two independent passageways.

A fluid pathway can be created between the male luer port and one, and only one, of the three female ports. This is achieved by rotating the stem/handle to one of three distinct positions. The word "ON" located on the stem/handle signifies which ports are connected. In either extreme handle position, the handle straddles the two ports which are connected. In the center position, the handle aligns with and indicates a straight flow pathway.

Similar in intended use to the selected legally marketed devices, the Tri-Flow™ 3-Way Stopcock is designed to be used in any medical procedure where controlled flow of fluid is required. It is specifically designed to be used in procedures where three different fluids are administered into one line.

The technological characteristics of the device are substantially equivalent to those of the above mentioned legally marketed stopcocks. The mode of operation and user interface are substantially equivalent. Device dimensions are substantially equivalent. The Tri-Flow™ 3-Way Stopcock is a relatively simple device with no exceptional material requirements. The materials selected are identical to those used in the above referenced legally marketed devices.



Jim Pokorney, President, North, Inc.

11/27/96

Date